PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the Application of:	)	
	)	Atty. Docket No. 00-1278
Lawton *et al.*	)	
	)	Art Unit: 1645
Serial No.: **09/765,739**	)	
	)	Examiner: V. Ford
Filed: **January 18, 2001**	)	
	)	Conf. No.: 9509

For: **Compositions and Methods for Detection of *Ehrlichia canis* and *Ehrlichia chaffeensis* Antibodies**

REPLY BRIEF

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REPLY BRIEF

Mail Stop: Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Reply Brief is filed in response to the Examiner's Answer mailed on November 3, 2004. It is believed that no fee is due in connection with this filing; however, if a fee is due the Commissioner is authorized to charge our Deposit Account No. 13-2490.

Contents

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REAL PARTY IN INTEREST

The real party in interest is IDEXX Laboratories, Inc., Westbrook, Maine, to whom this invention is assigned.

RELATED APPEALS AND INTERFERENCES

Related appeals have been filed in U.S. Application 10/054,647 and U.S. Application 10/054,354, both of which are divisionals of the present application. Appellant is aware of no other related appeals, interferences, or judicial proceedings concerning this application.

STATUS OF CLAIMS

Claims 21-24 and 39-42 are pending and stand rejected. Claims 1-20 and 25-34 have been withdrawn. Claims 35-38 have been cancelled.

STATUS OF AMENDMENTS

An amendment after final was presented on February 17, 2004. Claims 39 and 41 were amended. The amendment was entered according to the Advisory Action issued on May 26, 2004. No further amendments were presented after final.

SUMMARY OF CLAIMED SUBJECT MATTER

The invention provides a device containing one or more polypeptides consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and amino acid substitution variants thereof that specifically bind to an anti-*Ehrlichia* antibody. *See e.g.*, page 4, lines 1-5; page 5, lines 11-13; page 7, lines 14-17; page 8, line 21 through page 9, line 1; page 9, lines 8-11; page 15, lines 19-22; Table I. The device can comprise instructions for use of the one or more

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polypeptides for the identification of an *Ehrlichia* infection in a mammal. *See e.g.,* page 4, lines 1-5; page 15, lines 19-22. The instructions for use can indicate that the identification of an *Ehrlichia* infection is done using a method of detecting presence of antibodies to *Ehrlichia* comprising:

(a) contacting one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and amino acid substitution variants thereof that specifically bind to an anti-*Ehrlichia* antibody, with a test sample suspected of comprising antibodies to *Ehrlichia*, under conditions that allow polypeptide/antibody complexes to form;

(b) detecting polypeptide/antibody complexes;

wherein the detection of polypeptide/antibody complexes is an indication that an *Ehrlichia* infection is present. *See e.g.,* page 3, lines 16-23; page 5, lines 11-13; page 7, lines 14-17; page 8, line 21 through page 9, line 1; page 9, lines 8-11; page 12, lines 5-16; Table 1.

The *Ehrlichia* infection can be caused by *Ehrlichia canis* or *Ehrlichia chaffeensis*. See e.g., page 11, lines 22-23.

The invention also provides a device containing one or more polypeptides selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7 that specifically bind to an anti-*Ehrlichia* antibody. *See e.g.,* page 4, lines 1-5; page 5, lines 11-13; page 7, lines 14-17; page 8, line 21 through page 9,

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line 1; page 9, lines 8-11; page 15, lines 19-22; Table I. The device can further comprise instructions for use of the one or more polypeptides for the identification of an *Ehrlichia* infection in a mammal. *See e.g.,* page 4, lines 1-5; page 15, lines 19-22. The instructions for use indicate that the identification of an *Ehrlichia* infection can be done using a method of detecting presence of antibodies to *Ehrlichia* comprising:

> (a) contacting one or more polypeptides selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, that specifically bind to an anti-*Ehrlichia* antibody, with a test sample suspected of comprising antibodies to *Ehrlichia*, under conditions that allow polypeptide/antibody complexes to form;
>
> (b) detecting polypeptide/antibody complexes;
>
> wherein the detection of polypeptide/antibody complexes is an indication that an *Ehrlichia* infection is present. *See e.g.,* page 3, lines 16-23; page 5, lines 11-13; page 7, lines 14-17; page 8, line 21 through page 9, line 1; page 9, lines 8-11; page 12, lines 5-16; Table 1.

The *Ehrlichia* infection can be caused by *Ehrlichia canis* or *Ehrlichia chaffeensis.* See e.g., page 11, lines 22-23.

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GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

I. Claims 39-42 stand as rejected under 35 U.S.C. §102(a), as allegedly anticipated by Waner *et al.* J. Vet. Diagn. Invest., 2000, 12:240-244 ("Waner");

II. Claims 21-24 and 39-42 stand as rejected under 35 U.S.C. 102(a) as allegedly anticipated by Cadman *et al.,* Vet. Record, 1994, 135:362 ("Cadman"); and

III. Claims 21-24 stand as rejected under 35 U.S.C. 102(a) as allegedly anticipated by Rikihisa, WO99/13720.

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ARGUMENT

I. Claims 39-42 are not anticipated by Waner under 35 U.S.C. §102(a).

Claims 39-42 stand rejected under 35 U.S.C. §102(a) as anticipated by Waner. Applicants respectfully traverse the rejection.

The claims recite a device containing one or more polypeptides selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, that specifically bind to an anti-*Ehrlichia* antibody.

The claims recite *E. chaffeensis* polypeptides and Waner teaches whole *E. can*is proteins and cells. The Examiner's Answer states that the claims do not require that the polypeptides are derived from any particular *Ehrlichia* species. It is the Examiner's position that Waner reads on the claimed device because the device could contain more than one polypeptide since the claims recite open claim language. However, in order for Waner to anticipate claims 39-42, Waner **must** teach, inherently or directly, the polypeptides of SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7. While the claims do not recite that these polypeptides must be derived from a particular *Ehrlichia* species, the fact is that these polypeptides are indeed *Ehrlichia chaffeensis* polypeptides. See specification, page 6, Table.

Waner clearly does not teach or suggest **any** *E. chaffeensis* polypeptides; rather Waner teaches the use of *E. canis* whole proteins and whole cells. The Examiner has not provided any reasoning as to why Waner, which teaches methods and compositions for

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detecting *E. canis* using *E. canis* cells and proteins, would anticipate a device containing *E. chaffeensis* polypeptides.

Even if the Examiner were to assert that the *E. canis* polypeptides are the same as the *E. chaffeensis* polypeptides, the specification provides evidence that *E. canis* polypeptides and *E. chaffeensis* polypeptides are not the same. See specification, page 6, Table and Table 1 of this paper (see page 10). In Table 1 of this paper, polypeptide sequences of *E. canis* and *E. chaffeensis* are aligned. It can be seen that *E. canis* polypeptides and *E. chaffeensis* polypeptides are not the same.

Waner does not anticipate claims 39-42 because Waner does not teach, suggest, or inherently disclose each and every element of claims 39-42. Applicants respectfully request withdrawal of the rejection.

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Table 1.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
SEQ ID NO:1 *E. canis*	K	S	T	V	G	V	E	G	L	K	H	D	W	D	G	S	P	I	L	K
SEQ ID NO:2 *E. canis*	N	T	T	T	G	V	F	G	L	K	Q	D	W	D	G	A	T	I	K	D
SEQ ID NO:3 *E. chaffeensis*	N	T	T	V	G	V	E	G	L	K	Q	N	W	D	G	S	A	I	S	N
SEQ ID NO:4 *E. chaffeensis*	N	P	T	V	A	L	Y	G	E	K	Q	D	W	N	G	V	S	A		
SEQ ID NO:5 *E. chaffeensis*	N	T	T	V	G	V	E	G	L	E	Q	D	W	D	R	C	V	I	S	
SEQ ID NO:6 *E. chaffeensis*	N	P	T	V	A	L	Y	G	E	K	Q	D	W	E	G	I	S	S		
SEQ ID NO:7 *E. chaffeensis*	N	T	T	T	G	V	E	G	L	K	Q	D	W	D	G	S	T	I	S	

Dark grey shading indicates amino acid residues that are the same for the given amino acid position.
Light grey shading indicates that only two different amino acid residues are present for that amino acid position.

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II. Claims 21-24 and 39-42 are not anticipated by Cadman under 35 U.S.C. §102(a).

Claims 21-24 and 39-42 stand rejected under 35 U.S.C. §102(a) as allegedly anticipated by Cadman. Applicants respectfully traverse the rejection.

A. Claims 21-24.

Claims 21-24 recite devices containing one or more polypeptides consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and amino acid substitution variants thereof that specifically bind to an anti-*Ehrlichia* antibody.

The Examiner's answer states that the Examiner is interpreting the claims to read on a device comprising one or more polypeptides as well as substitution variants that bind to anti-*Ehrlichia* antibody. The Examiner therefore concludes that the claims read on whole cells and whole proteins. However, the claims clearly recite that the device contains "one or more polypeptides **consisting of** SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7." While Appellants agree that the device can contain additional polypeptides, Appellants point out that Cadman **must** still teach one or more polypeptides **consisting of** SEQ ID NOs:1-7.

The Examiner's answer has not provided reasoning as to why the claims read on whole cells and whole proteins other than the claims are being interpreted to read on a device comprising one or more polypeptides as well as substitution variants that bind to anti-*Ehrlichia* antibody.

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The preamble of the claims recite "A device containing one or more polypeptides." "Containing" is considered an "open" claim term. *See e.g., Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1375; 71 USPQ2d 1837, 1841-1842 (Fed. Cir. 2004). Therefore, the device is inclusive or open-ended and does not exclude additional unrecited elements. The claim then goes on to specify that the device contains "one or more polypeptides **consisting of** SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and amino acid substitution variants thereof." The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. *See, e.g., AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239, 1245; 57 USPQ2d 1776, 1780 (Fed. Cir. 2001).

Importantly, where the phrase "consists of" appears in a clause of the body of a claim, rather than immediately following the preamble, it limits only the element set forth in that clause. Other elements are not excluded from the claim as a whole. *See e.g., Mannesmann Demag Corp. v. Engineered Metal Products Co.,* 793 F.2d 1279, 1282-1283; 230 USPQ 45, 46 (Fed. Cir. 1986).

In the instant case the phrase "consisting of" appears in a clause of the body of the claim, rather than immediately following the preamble. Therefore, "consists of" limits the following clause: "SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and amino acid substitution variants thereof." Thus, any unrecited element, step, or ingredient is excluded from this phrase. That is, the recited polypeptide sequences cannot be interpreted to include *Ehrlichia*

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whole cells or whole proteins. As such, Cadman, which only teaches *E. canis* whole cells and whole proteins, does not teach or suggest the recited polypeptides.

Additionally, the Examiner's Answer states that the Declaration of Dr. Chandrashekar does not overcome the instant rejection because the issues discussed in the declaration, *i.e.,* sensitivity and specificity of the recited polypeptides, are not present in the claims. The Declaration was presented to demonstrate that recited polypeptides do indeed have unique properties as compared to the whole cells and whole proteins taught in Cadman.

The Examiner's Answer states that the claims do not require that the polypeptides are derived from any particular *Ehrlichia* species. However, in order for Cadman to anticipate claims 21-24, specifically, SEQ ID NOs:3-7, Cadman **must** teach, inherently or directly, the polypeptides of SEQ ID NOs:3-7. While the claims do not recite that these polypeptides must be derived from a particular *Ehrlichia* species, the fact is that these polypeptides of SEQ ID NOs:3-7 are indeed *Ehrlichia chaffeensis* polypeptides. See specification, page 6, Table.

Cadman clearly does not teach or suggest **any** *E. chaffeensis* polypeptides; rather Cadman teaches the use of *E. canis* polypeptides. The Examiner has not provided any reasoning as to why Cadman, which teaches methods and compositions for detecting *E. canis* using *E. canis* cells and proteins, would anticipate a device containing *E. chaffeensis* polypeptides of SEQ ID NOs: 3-7.

Even if the Examiner were to assert that the *E. canis* polypeptides are the same as the *E. chaffeensis* polypeptides, the specification provides evidence that *E. canis*

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polypeptides and *E. chaffeensis* polypeptides are not the same. See specification, page 6, Table and Table 1 of this paper (see page 10). In Table 1 of this paper, polypeptide sequences of *E. canis* and *E. chaffeensis* are aligned. It can be seen that *E. canis* polypeptides and *E. chaffeensis* polypeptides are not the same.

B. Claims 39-24

Claims 39-42 recite devices containing one or more polypeptides selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, that specifically bind to an anti-*Ehrlichia* antibody.

The claims recite *E. chaffeensis* polypeptides and Cadman teaches *E. canis* whole proteins and whole cells. The Examiner's Answer states that the claims do not require that the polypeptides are derived from any particular *Ehrlichia* species. It is the Examiner's position that Cadman reads on the claimed invention because the device could contain more than one polypeptide since the claims recite open claim language. However, in order for Cadman to anticipate claims 39-42, Cadman **must** teach, inherently or directly, the polypeptides of SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7. While the claims do not recite that these polypeptides must be derived from a particular *Ehrlichia* species, the fact is that these polypeptides are indeed *Ehrlichia chaffeensis* polypeptides. See specification, page 6, Table 1.

Cadman clearly does not teach or suggest **any** *E. chaffeensis* polypeptides; rather Cadman teaches the use of *E. canis* whole cells and whole proteins. The Examiner has not provided any reasoning as to why Cadman, which teaches methods and compositions

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for detecting *E. canis* using *E. canis* cells and proteins, would anticipate a device containing *E. chaffeensis* polypeptides.

Even if the Examiner were to assert that the *E. canis* polypeptides are the same as the *E. chaffeensis* polypeptides, the specification provides evidence that *E. canis* polypeptides and *E. chaffeensis* polypeptides are not the same. See specification, page 6, Table and Table 1 of this paper (see page 10). In Table 1 of this paper, polypeptide sequences of *E. canis* and *E. chaffeensis* are aligned. It can be seen that *E. canis* polypeptides and *E. chaffeensis* polypeptides are not the same.

Cadman does not teach each and every element of the claimed invention and therefore does not anticipate the claimed invention. Applicants respectfully request withdrawal of the rejection.

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III. Claims 21-24 are not anticipated by Rikihisa under 35 U.S.C. §102(b).

Claims 21-24 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Rikihisa. Applicants respectfully traverse the rejection.

Claims 21-24 recite devices containing one or more polypeptides consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and amino acid substitution variants thereof that specifically bind to an anti-*Ehrlichia* antibody.

The Examiner's answer states that the Examiner is interpreting the claims to read on a device comprising one or more polypeptides as well as substitution variants that bind to anti-*Ehrlichia* antibody. The Examiner therefore concludes that the claims read on whole cells and whole proteins. However, the claims clearly recite that the device contains "one or more polypeptides **consisting of** SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7." While Appellants agree that the device can contain more than polypeptides of the cited SEQ ID NOs, Appellants point out that Rikihisa **must** still teach one or more polypeptides **consisting of** SEQ ID NOs:1-7.

The Examiner's answer has not provided reasoning as to why the claims read on whole proteins other than the claims are being interpreted to read on a device comprising one or more polypeptides as well as substitution variants that bind to anti-*Ehrlichia* antibody.

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As discussed above, the preamble of the claim recites "A device containing one or more polypeptides," and "containing" is considered to be an "open" claim term. Therefore, the device is inclusive or open-ended and does not exclude additional unrecited elements. The claim then goes on to specify that the device contains "one or more polypeptides **consisting of** SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and amino acid substitution variants thereof."

Importantly, where the phrase "consists of" appears in a clause of the body of a claim, rather than immediately following the preamble, it limits only the element set forth in that clause. Other elements are not excluded from the claim as a whole. In the instant case, the phrase "consisting of" appears in a clause of the body of the claim, rather than immediately following the preamble.

Therefore, "consists of" limits the following clause: "SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and amino acid substitution variants thereof." Therefore, any unrecited element, step, or ingredient is excluded from this phrase. That is, the recited polypeptide sequences cannot be interpreted to include *Ehrlichia* whole cells or whole proteins. As such, Rikihisa, which only teaches whole proteins does not teach or suggest the recited polypeptides.

Importantly, the addition of amino acids to the polypeptides of they invention so they encompass the whole proteins of Rikihisa would materially affect the characteristics of the polypeptides of the invention. That is, use of full-length proteins would result in assays that are less sensitive than those disclosed in the instant specification. See

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declaration of Dr. Chandrashekar (of record). As such, the claims cannot be read so that the whole proteins of Rikihisa anticipates the claimed fragments.

Rikihisa does not anticipate claims 21-24 because Rikihisa does not teach, suggest, or inherently disclose each and every element of claims 21-24. Applicants respectfully request withdrawal of the rejection.

For the foregoing reasons, the examiner's rejections of claims 21-24 and 39-42 should be reversed.

Respectfully submitted,

Date: 12/28/04 By: _____

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CLAIMS APPENDIX

Pending Claims

1. (Withdrawn) A composition of matter comprising an isolated polypeptide selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7 and variants thereof.

2. (Withdrawn) The composition of claim 1, further comprising a carrier.

3. (Withdrawn) A method of detecting presence of antibodies to Ehrlichia comprising:

(a) contacting one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and variants thereof, with a test sample suspected of comprising antibodies to Ehrlichia, under conditions that allow polypeptide/antibody complexes to form;

(b) detecting polypeptide/antibody complexes;

wherein the detection of polypeptide/antibody complexes is an indication that antibodies to Ehrlichia are present in the test sample.

4. (Withdrawn) The method of claim 3, further comprising contacting the complexes of step (a) with an indicator reagent comprising a signal generating compound that generates a measurable signal prior to the performance of step (b).

5. (Withdrawn) The method of claim 3, wherein the presence of antibodies to *Ehrlichia canis* are detected.

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6. (Withdrawn) The method of claim 3, wherein the presence of antibodies to *Ehrlichia chaffeensis* are detected.

7. (Withdrawn) The method of claim 3, wherein the antibodies are fragments of antibodies.

8. (Withdrawn) The method of claim 3 wherein the amount of antibody in a test sample is determined.

9. (Withdrawn) The method of claim 3, wherein the polypeptide is attached to a substrate.

10. (Withdrawn) The method of claim 3, wherein the polypeptide provided is shown in SEQ ID NO:1.

11. (Withdrawn) The method of claim 3, wherein the polypeptide provided is shown in SEQ ID NO:2.

12. (Withdrawn) The method of claim 3, wherein the polypeptide provided is shown in SEQ ID NO:3.

13. (Withdrawn) The method of claim 3, wherein the polypeptide provided is shown in SEQ ID NO:4.

14. (Withdrawn) The method of claim 3, wherein the polypeptide provided is shown in SEQ ID NO:5.

15. (Withdrawn) The method of claim 3, wherein the polypeptide provided is shown in SEQ ID NO:6.

16. (Withdrawn) The method of claim 3, wherein the polypeptide provided is shown in SEQ ID NO:7.

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17. (Withdrawn) The method of claim 3, wherein the one or more polypeptides are provided in a multimeric form.

18. (Withdrawn) The method of claim 3, wherein the test sample is a biological sample obtained from a mammal.

19. (Withdrawn) The method of claim 18, wherein the mammal is selected from the group consisting of humans and dogs.

20. (Withdrawn) The method of claim 3 wherein the method comprises an assay selected from the group of assays consisting of a reversible flow chromatographic binding assay, an enzyme linked immunosorbent assay, a western blot assay, and an indirect immunofluorescense assay.

21. (Previously Presented) A device containing one or more polypeptides consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and amino acid substitution variants thereof that specifically bind to an anti-*Ehrlichia* antibody.

22. (Previously Presented) The device of claim 21, further comprising instructions for use of the one or more polypeptides for the identification of an *Ehrlichia* infection in a mammal.

23. (Previously Presented) The device of claim 22, wherein the instructions for use indicate that the identification of an *Ehrlichia* infection is done using a method of detecting presence of antibodies to *Ehrlichia* comprising:

(a) contacting one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ

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ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and amino acid substitution variants thereof that specifically bind to an anti-*Ehrlichia* antibody, with a test sample suspected of comprising antibodies to *Ehrlichia*, under conditions that allow polypeptide/antibody complexes to form;

(b) detecting polypeptide/antibody complexes;

wherein the detection of polypeptide/antibody complexes is an indication that an *Ehrlichia* infection is present.

24. (Previously Presented) The device of claim 22, wherein the *Ehrlichia* infection is caused by *Ehrlichia canis* or *Ehrlichia chaffeensis*.

25. (Withdrawn) An article of manufacture comprising packaging material and, contained within the packaging material, one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and variants thereof.

26. (Withdrawn) The article of manufacture of claim 25 wherein the packaging material comprises a label that indicates that the one or more polypeptides can be used for the identification of Ehrlichia infection in a mammal.

27. (Withdrawn) The article of manufacture of claim 26, wherein the identification of an Ehrlichia infection is done using a method of detecting presence of antibodies to Ehrlichia comprising:

(a) contacting one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and variants thereof, with a test sample

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suspected of comprising antibodies to Ehrlichia, under conditions that allow polypeptide/antibody complexes to form;

(b) detecting polypeptide/antibody complexes;

wherein the detection of polypeptide/antibody complexes is an indication that an Ehrlichia infection is present.

28. (Withdrawn) The article of manufacture of claim 26, wherein the Ehrlichia infection is caused by *Ehrlichia canis* or *Ehrlichia chaffeensis.*

29. (Withdrawn) A method of diagnosing an Ehrlichia infection in a mammal comprising:

(a) obtaining a biological sample from a mammal suspected of having an Ehrlichia infection;

(b) contacting one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, and variants thereof, with the biological sample under conditions that allow polypeptide/antibody complexes to form;

(c) detecting polypeptide/antibody complexes;

wherein the detection of polypeptide/antibody complexes is an indication that the mammal has an Ehrlichia infection.

30. (Withdrawn) The method of claim 29 further comprising contacting the complexes of step (b) with an indicator reagent comprising a signal generating compound that generates a measurable signal prior to the performance of step (c).

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31. (Withdrawn) The method of claim 29, wherein the Ehrlichia infection is caused *by Ehrlichia canis.*

32. (Withdrawn) The method of claim 29, wherein the Ehrlichia infection is caused by *Ehrlichia chaffeensis.*

33. (Withdrawn) The method of claim 29, wherein the mammal is a human or a dog.

34. (Withdrawn) A monoclonal antibody that specifically binds to at least one epitope of an *Ehrlichia canis* or *Ehrlichia chaffeensis* polypeptide, said polypeptide selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, and SEQ ID NO:7.

35. (Canceled)

36. (Canceled)

37. (Canceled)

38. (Canceled)

39. (Previously Presented) A device containing one or more polypeptides selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, that specifically bind to an anti-*Ehrlichia* antibody.

40. (Previously Presented) The device of claim 39, further comprising instructions for use of the one or more polypeptides for the identification of an *Ehrlichia* infection in a mammal.

41. (Previously Presented) The device of claim 39, wherein the instructions for use indicate that the identification of an *Ehrlichia* infection is done using a method of detecting presence of antibodies to *Ehrlichia* comprising:

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(a) contacting one or more polypeptides selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO:6, SEQ ID NO:7, that specifically bind to an anti-*Ehrlichia* antibody, with a test sample suspected of comprising antibodies to *Ehrlichia*, under conditions that allow polypeptide/antibody complexes to form;

(b) detecting polypeptide/antibody complexes;

wherein the detection of polypeptide/antibody complexes is an indication that an *Ehrlichia* infection is present.

42. (Previously Presented) The device of claim 39, wherein the *Ehrlichia* infection is caused by *Ehrlichia canis* or *Ehrlichia chaffeensis*.

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